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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/647,131

08/22/2003

Neil H. Riordan

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02/14/2006

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EXAMINER

MELLER, MICHAEL V

ART UNIT

PAPER NUMBER

1655

DATE MAILED: 02/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/647,131

Applicant(s)

RIORDAN, NEIL H.

Examiner

Michael V. Meller

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1655

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 6-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 19-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-5, drawn to a composition, classified in class 424, subclass various.
- II. Claims 6-18, drawn to a method of using the composition, classified in class 435, subclass various.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially distinct process such as treating wounds.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention: the many different fibrinolytic agents and antioxidants.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

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the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Suzanne Jepson on 7/7/2005 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-5, pine bark extract and nattokinase. Affirmation of this election must be made by applicant in replying to this Office action. Claims 6-18 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant's election with traverse of Group I, claims 1-5, nattokinase and pine bark extract in the reply filed on 11/14/2005 is acknowledged. The traversal is on the ground(s) that there is no burden to search claims 6-18 if claims 1-5 and newly presented claims 19-25 are found allowable. This is not found persuasive because claims 1-5 and 19-25 are not allowable.

The requirement is still deemed proper and is therefore made FINAL.

This application contains claims 6-18 are drawn to an invention nonelected with traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5 and 19-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moriyama et al. in view of Rohdewald and further in view of JP 55081816.

Moriyama teaches that an enterically coated capsule is used to inhibit platelet aggregation. Moriyama also shows that nattokinase is known as a thrombolytic enzyme and this thrombolytic activity has been known to be excellent not only for preventing thrombosis but also for treating it, see col. 4, title.

This reference does not teach using pine bark extract along with the nattokinase.

Rohdewald teaches that pine bark extract (*pinus maritima*) is used to inhibit platelet aggregation and is used at a concentration of 200-500 mg, see col. 2, lines 45-60.

JP 55081816 shows that it is known to use coated tablets of pine bark extract, see abstract.

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It would have been obvious to combine the nattokinase of Moriyama with the pine bark extract of Rohdewald in the same composition since the references both teach that the pine bark extract or the nattokinase are both used to inhibit platelet aggregation.

It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Sussman*, 1943 C.D. 518; *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

The reason or motivation to modify a reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. While there must be motivation to make the claimed invention, there is no requirement that the prior art provide the same reason as the applicant to make the claimed invention.

MPEP 2144 Sources of Rationale Supporting a Rejection Under 35 U.S.C. 103.
<http://www.uspto.gov/web/offices/pac/mpep/documents/2100_2144.htm>

Thus, it would have been obvious for one of ordinary skill in the art to add the pine bark and the natto kinase to form one single composition since they were both individually known in the art to be used for the same purpose, namely to be used to inhibit platelet aggregation.

The JP reference makes it clear that coating tablets is known in the art.

It is not clear what the fibrinolytic unit amount refers to in the nattokinase and there is no way to compare it to the amounts of nattokinase used in the references.

The range in claim 24 is so broad that it is clearly encompassed by the disclosures of the references.

Claims 1-5 and 19-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sumi et al. in view of Rohdewald and further in view of JP 55081816.

Sumi teaches coated capsules of nattokinase are administered to dogs to treat thrombosis, see abstract.

This reference does not teach using pine bark extract along with the nattokinase.

Rohdewald teaches that pine bark extract (*pinus maritima*) is used to inhibit platelet aggregation and is used at a concentration of 200-500 mg, see col. 2, lines 45-60.

JP 55081816 shows that it is known to use coated tablets of pine park extract, see abstract.

It would have been obvious to combine the nattokinase of Sumi with the pine bark extract of Rohdewald in the same composition since the references both teach that the pine bark extract or the nattokinase are both used because of the known fibinolytic

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activity of the nattokinase and the pine bark which will lyse a thrombi. In both Rohdewald and Sumi a blockage is occurring which is desired to be removed by lysis with a fibrinolytic agent which will lyse the blockage thus clearing the vein or artery for proper blood flow.

It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Sussman*, 1943 C.D. 518; *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

The reason or motivation to modify a reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. While there must be motivation to make the claimed invention, there is no requirement that the prior art provide the same reason as the applicant to make the claimed invention.

MPEP 2144 Sources of Rationale Supporting a Rejection Under 35 U.S.C. 103.
<http://www.uspto.gov/web/offices/pac/mpep/documents/2100_2144.htm>

Thus, it would have been obvious for one of ordinary skill in the art to add the pine bark and the natto kinase to form one single composition since they were both individually known in the art to be used for the same above purpose.

The JP reference makes it clear that coating tablets is known in the art.

It is not clear what the fibrinolytic unit amount refers to in the nattokinase and there is no way to compare it to the amounts of nattokinase used in the references.

The range in claim 24 is so broad that it is clearly encompassed by the disclosures of the references.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-

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0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael V. Meller
Primary Examiner
Art Unit 1655

MVM